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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/597,842 | 10/12/2007 | Georg Duda | 10139/16101 (00886-06PUS1) | 6992 |
| 76960 | 7590 | 02/22/2010 | EXAMINER | |
| Fay Kaplun & Marcini, LLP 150 Broadway, suite 702 New York, NY 10038 | | | BECCIA, CHRISTOPHER J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3775 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/22/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/597,842 | DUDA ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER BECCIA | 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-17 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-17 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/3/09 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant has submitted replacement drawings. Examiner's objection has been withdrawn.
2. Claims 2-20 have been amended to address typographical errors. Examiner's objection has been withdrawn.
3. Claims 5-20 have been amended to correct dependency errors. The objection to Claims 5-6 and 8-17, has been withdrawn, and will be further treated on the merits.
4. Applicant's arguments with respect to claims 1-4 have been considered and are addressed within the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-6, 8-17 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2002/0151770 to *Noll et al.* in view of U.S. Patent No. 6,464,687 to *Ishikawa et al.* in further view of in view of U.S. Patent No. 6,464,687 to *Karpman et al.*

As to **Claim 1**, *Noll* discloses a component for an arrangement at an implant (See Fig. 10), comprising: a basic component (30) including; at least one sensor device (16) detecting a measurement variable and generating measuring data for the detected

measurement variable [0037]; a telemetry device (88, 20 and 60) at least one of transmitting and receiving data [0040]; and a data transmission connection (60) arranged in the basic component between the at least one sensor device and the telemetry device for the transmission of data therebetween the data including the measuring data [0040], whereby the data comprise the measuring data [0044]; an assembly arrangement (30), assembly detachably mounting the basic component in an implant recess of the implant [0063-0064].

As to **Claim 2**, *Noll* discloses a component wherein in that the assembly arrangement includes an assembly section configured to be at least partially inserted into the implant recess (48 in Fig. 10 and [0063]).

As to **Claim 3**, *Noll* discloses a component further comprising, in the zone of the assembly section, a threaded section (42) configured to be screwed into the implant recess [0058].

As to **Claim 4**, *Noll* discloses a component wherein the basic component has in a longitudinal section an essentially T-shaped cross-section with a head part and a base part (See Fig. 10).

As to **Claim 5**, *Noll* discloses a component wherein the at least one sensor device (16) is arranged in the zone of the first end section of the basic component and the telemetry device (20) is arranged in a zone of an oppositely located second end section of the basic component (Fig. 10) and [0066].

As to **Claim 6**, *Noll* discloses a component wherein the telemetry device is essentially arranged in the head part of the basic component (20, Fig. 10).

As to **Claims 1**, *Noll* discloses the claimed invention except for a receiving chamber located within the basic component and configured to accommodate an active ingredient therein, the receiving chamber extending to an opening at a first end section of the basic component for discharging the active ingredient therefrom.

Ishikawa discloses an implantable drug delivery system (400, Col. 2, Lines 28-36) wherein a receiving chamber (402) located within the basic component and configured to accommodate an active ingredient therein, the receiving chamber extending to an opening at a first end section of the basic component for discharging the active ingredient therefrom (Col. 11, Lines 22-52); a discharge device (406) configured to control discharging of the active ingredient from the receiving chamber through the opening (Abstract); wherein the discharge device comprises (406) includes a pump device pumping a volume of the active ingredient from the receiving chamber through the opening (Abstract); wherein the discharge device includes an opening mechanism opening/closing the opening (Col. 9, Lines 31-50); wherein the discharge device is connected using a further data transmission connection to the telemetry device for the transmission of data (Col. 9, Lines 50-67 – Col. 10, Lines 1-18); a control unit connected to the at least one sensor device and the discharge device to control the detection of the measuring data using the at least one sensor device and the discharge of the active ingredient with using the discharge device (Col. 9, Lines 31-50– Col. 10, Lines 1-18) in order to provide a drug storage medium, capable of being discharged under control of a sensor system (Col. 2, Lines 28-35).

Karpman discloses an implantable drug delivery system (230, Fig. 6) comprising a supporting implant (239); wherein the component (230) is configured to be arranged in an implant recess extending through the supporting implant (Fig. 6, Col. 11, Lines 14-37) wherein the implant recess is a usable assembly recess configured to accommodate an implant fixation device (Fig. 6, Col. 11, Lines 14-37); wherein the implant recess has a internal thread section (239, Fig. 6); wherein the supporting implant is one of a synthetic hip, a knee and a shoulder joint plate (Col. 5, Lines 5-14); wherein the supporting implant is one of a plate (239) and a splint formed of a material with a high degree of rigidity (Col. 11, Lines 14-37) in order to provide a plate for securing the drug delivery component into the desired location within the body (Col. 11, Lines 14-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the component for an arrangement at an implant of *Lum* with the drug delivery modifications of *Ishikawa* and stabilization plate of *Karpman* in order to provide a drug storage medium, capable of being discharged under control of a sensor system, and a plate for securing the drug delivery component into the desired location within the body.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775